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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

THE JOHNS HOPKINS UNIVERSITY, a Maryland corporation. BAXTER HEALTHCARE CORPORATION, a Delaware corporation, and BECTON DICKINSON AND COMPANY, a New Jersey corporation,	:	Case No. 94-105 RRM
Plaintiffs.	:	
v.	:	
CELLPRO, INC., a Delaware corporation,	:	
Defendant.	:	

SUPPLEMENTAL DECLARATION OF DR. MONICA S. KRIEGER IN OPPOSITION TO PLAINTIFFS' MOTION FOR PERMANENT INJUNCTION AND IN SUPPORT OF ALTERNATIVE MOTION FOR STAY OF INJUNCTION

I, MONICA S. KRIEGER, Ph.D., hereby declare as follows:

1. I am the Director of Regulatory Affairs at CellPro, Inc., Bothell, Washington. I have personal knowledge of the matters set forth in this declaration and if called as a witness could competently testify thereto.

2. I am informed and believe that during oral argument on plaintiffs' permanent injunction motion held April 30, 1997, plaintiffs produced and handed to the court a copy of a letter which I received from the FDA in January 1997, a copy of which is attached hereto as **EXHIBIT A.** The handwritten notation at the top of the first page is mine, added after the letter was received at CellPro. I caused the letter, with my handwritten notation, to be circulated internally within CellPro but I gave no one permission (and to the best of my knowledge no one else at CellPro gave anyone permission) to disseminate the letter outside the company. The version of the letter containing my handwritten notation was not obtainable by the plaintiffs from any public-record source, and could only have come into plaintiffs' hands as a result of having been improperly divulged by someone from CellPro.

3. Attached hereto as **EXHIBIT B** is an original specimen of the Christmas card to which the FDA's letter pertains.

4. I understand that plaintiffs' counsel, at the April 30, 1997 hearing, argued that the FDA's letter is evidence of disapproval by the FDA of off-label uses of the CellPro

CEPRATE® SC stem cell concentration system apart from "an authorized IDE." In fact, the use reported in the Christmas card was made under, and not apart from, an authorized IDE. As the text of the Christmas card suggests, the child "guest artist" was enrolled for treatment of acute myelocytic leukemia (AML) in the course of an investigation under the direction of Dr. Andrew M. Yeager at Emory University, after his parents found out that physician-investigators at Emory were involved in a clinical trial evaluating stem cell transplants from half-matched (haploidentical) parents to children. The "Dr. Yeager" referenced in the Christmas card is, in fact, the same Dr. Yeager who submitted a declaration in this case on CellPro's behalf, and the clinical trial in which the "Christmas card" child was treated is in fact the same FDA-approved clinical trial which Dr. Yeager described at paragraph 3 of that declaration. In other words, the Christmas card, and the FDA's reaction to it, tell nothing whatsoever about what FDA's view, if any, might be toward off-label uses apart from authorized IDEs. The use in this situation was under, and not apart from, an authorized IDE, and the FDA's letter does not state that the use of the device to treat the child was in any way improper. Rather, the letter's expressed concern pertained to what the FDA termed "promotion" of the device via the Christmas card.

5. Attached hereto as **EXHIBIT C** is a true copy of my letter to the FDA in response to the FDA letter which is **EXHIBIT A**. Attached hereto as **EXHIBIT D** is a copy of a memo that I distributed to responsible personnel within CellPro. My purpose in doing so was to increase our company's vigilance in complying with the FDA's expectations as regards commercial statements concerning the CEPRATE® SC system.

6. The FDA's January 1997 letter to CellPro (**EXHIBIT** A) is what is known as an "untitled" letter. Although that letter was treated with due seriousness by CellPro, it should be noted that an "untitled" letter is the mildest form of written citation that the FDA issues. There is a recognized distinction between an "untitled letter" and a "warning letter," which is so titled and which denotes the FDA's view that a more serious infraction has taken place. Attached hereto as **EXHIBIT E** is a true copy of an excerpt from an FDA practice manual which explains the differences between an "untitled letter" and a "warning letter." Attached hereto as **EXHIBIT F** is an example of an FDA "warning letter," which was obtained under the Freedom of Information Act (FOIA). The letter, dated January 11, 1994 and addressed to the Chairman and CEO of Baxter Healthcare Corporation, reports the finding of an FDA investigation that Baxter's Bone Marrow Collection Kit was "misbranded" under the Federal Food, Drug and Cosmetic Act for failure to submit a Premarket Notification for significant changes made to the design of the device. As will be seen in the fourth paragraph of the letter, it threatens regulatory sanctions including seizure and/or injunction if prompt action is not taken to correct the violation. The January 1997 FDA letter **(EXHIBIT A)** received by CellPro, in contrast, is not entitled "warning letter" and does not contain a similar threat of regulatory sanctions. I have seen a number of additional FOIA-obtained titled FDA warning letters issued to Plaintiffs and related companies in the last five years.

7. I believe that CellPro's record of FDA regulatory compliance compares very favorably with those of Baxter, BD and related companies. In contrast to the titled warning letters mentioned above (and possibly others received by plaintiffs and related companies),

CellPro has never received a single warning letter, so titled, from the FDA.

8. As should be plain from **EXHIBIT F** and from the other warning letters mentioned above, infractions of FDA laws and rules, while regrettable, still occur with some frequency to health care firms larger, longer established, more experienced, more generously staffed and better financed than CellPro.

I declare under penalty of perjury that the foregoing is true and correct.

Executed at Bothell, Washington, this 23rd day of May 1997.

Monica S. Krieger

Monica S. Krieger, Ph.D.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD

This is an untitled letter from FDA -

RECEIVED
APR 10 1997
LAW DEPARTMENT

Rick suggested everyone have a copy so we understand the level of scrutiny we are under.)
Monica

Monica Krieger, Ph.D.
CellPro, Incorporated
22215 26th Avenue SE
Bothell, Washington 98021

Dear Dr. Krieger:

We are in receipt of a holiday greeting card that was disseminated by your company during the month of December, 1996. A copy is enclosed. Appearing on the back cover of the card is information about the artist which contains facts and efficacy claims related to a new indication for use of your CEPRATE® SC Stem Cell Concentration System for which a supplemental application has not been approved. As described in the conditions for approval of this device, no advertisement or other descriptive printed material issued by you or a distributor shall recommend or imply that the device may be utilized for uses that are not included in the FDA approved labeling.

The CEPRATE® SC Stem Cell Concentration System, manufactured by CellPro, Inc., is considered to be a device within the meaning of section 201(h) of the Federal Food Drug and Cosmetic Act (the Act). This device was approved for sale and distribution as a restricted device under the Premarket Approval (PMA) process described in section 515(d)(1)(B)(ii) of the Act for the following indication: [Reference PMA Number BP940001]:

"...for the processing of autologous bone marrow to obtain a CD34+ cell enriched population which is intended for hematopoietic support after myeloablative chemotherapy."

The specific areas of concern related to the promotion of this device are noted below.

a. In your "about the artist" profile, a brief discussion regarding the use of the CEPRATE system in allogeneic stem cell transplants appears in the second paragraph.

> The evaluation of stem cell transplants from allogeneic donors (e.g. use of stem cells from parents who are half-matched at tissue type antigens) is still experimental. Thus far, the Center for Biologics Evaluation and Research (CBER) has not received data from you that would render conclusive evidence to base your claim for use of the device in allogeneic transplants thereby expanding the donor pool and providing many more children with curative treatment of high risk leukemia. The new indication for use of this device described above may not be promoted until a PMA Supplement has been submitted and approved.

b. In the third paragraph of the "about the artist" profile, the following claim is made: "Selecting stem cells reduces the chances of severe graft-versus-host disease that would otherwise occur if a child were to receive a half-matched bone marrow transplant from a parent"

> CBER has not received a supplement to your PMA providing the clinical data that would provide the evidence needed to support this claim. In the absence of this information, one cannot conclude that CEPRATE®-selected (T- cell depleted) allogeneic transplants will prevent graft-versus-host disease or otherwise confer a benefit to the patient.

The above mentioned misrepresentations or like misrepresentations about the CellPro CEPRATE® device misbrand your product under Section 502(o) in that you have failed to comply with Section 515 of the Act. Section 515 of the Act requires that you file a PMA Supplement in accordance with the provisions described in 21 CFR Part 814.39. This regulation requires that an applicant submit a PMA Supplement before making a change affecting the safety or effectiveness of the device for which the applicant has an approved PMA. We have determined the aforementioned claims regarding the CEPRATE® system affect both the safety and

efficacy of this device and, therefore, require the submission of a supplement that would provide the definitive evidence to support such claims.

In addition, as a restricted device, you are further misbranding your device under Section 502(q)(1) of the Act, by including uses and claims in your advertising for this device that are regarded to be false and misleading

It is your responsibility to ensure that the violations noted in this letter that may appear in other advertising or promotional materials are also corrected. You should take prompt action to correct the violations noted and assure compliance with the applicable regulations.

Please respond to this staff, in writing, within 15 days of the receipt of this letter. Your response should include the steps you plan on taking to remedy the above noted observations. Please send your response to the attention of:

Ms. Toni M. Stiffano
Center for Biologics Evaluation and Research
Advertising and Promotional Labeling Staff, HFM-202
1401 Rockville Pike
Rockville, MD 20852-1448

Sincerely yours.

William V. Purvis
Director, Advertising and Promotional
Labeling Staff
Center for Biologics Evaluation
and Research

Enclosure

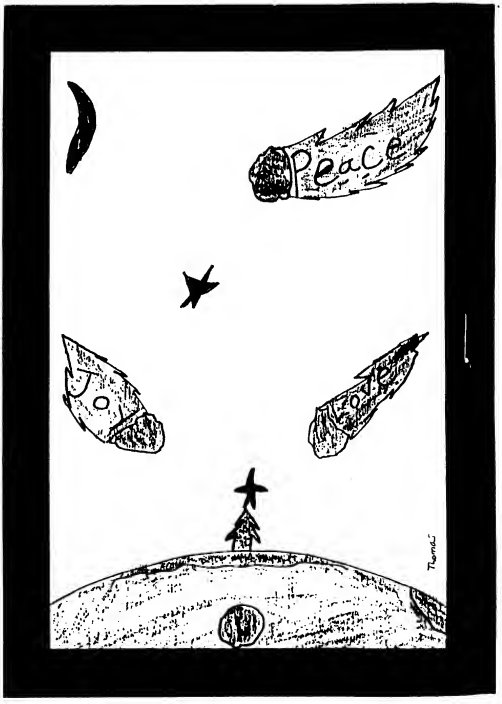
About the Artist

Thomas Green, our holiday guest artist, celebrated his ninth birthday in September 1996 and does just about all the things a healthy nine-year old does. But when he was six years old, Thomas was diagnosed with acute myelocytic leukemia (AML). He received intensive chemotherapy treatments, spent weeks in the hospital, and had problems with fevers and low blood counts. Although his AML initially responded to the chemotherapy, it relapsed just a few months later and required more intensive antileukemia drug treatments. Thomas was again in the hospital for treatment of complications like bloodstream infections, and he required numerous bone marrow tests and spinal taps in the clinic and in the hospital.

After further chemotherapy, his leukemia went into a second remission. Thomas's doctors knew that the best chance to cure his AML was with a bone marrow transplant. But Thomas's sister was not a tissue-type (HLA) match, and there was no time to find a suitable matched unrelated bone marrow donor. Faced with this dilemma, his family and doctors searched for other curative options. They found out that physician-investigators at the Pediatric Bone Marrow Transplant Program at Emory University and Egleston Children's Hospital in Atlanta were evaluating stem cell transplants from parents by children using the stem-cell selection technology pioneered by CellPro, Incorporated. Using parents, who are half-matched at the tissue-type antigens, as stem cell donors for their children greatly expands the donor pool and could provide many more children with curative treatment of high-risk leukemia.

A medical device developed by CellPro, called the CEPRATE® Stem Cell Concentration System, allowed the Emory physicians to select and purify the stem cells from Thomas's mother's bone marrow and peripheral blood cells. Selecting stem cells reduces the chances of severe graft-versus-host disease that would otherwise occur if a child were to receive a half-matched bone marrow transplant from a parent.

Under the direction of Andrew M. Yeager, M.D., Professor of Pediatrics and Medicine at Emory University, Thomas received a stem cell transplant from his mother, Nancy Green, in January 1995. Within two weeks after the stem cell transplant, Thomas's blood counts were returning to normal and there was no evidence of AML. Now almost two years after transplant, Thomas is off all medications, has normal blood counts, has no graft-versus-host disease, and – most importantly – has no AML. He's back leading a busy, normal life, balancing school, little league, and an avid interest in outer space. He even found a bit of spare time to provide the artwork for this holiday greeting from CellPro!



CellPro, Incorporated
22215 26th Avenue SE
Bothell, Washington 98021
(206) 485-7644
(206) 485-4787 Fax

February 10, 1997

Ms. Toni Stifano
Center for Biologics Evaluation and Research
Advertising and Promotional Labeling Staff, HFM-202
1401 Rockville Pike
Rockville, MD 20852-1448

Dear Ms Stifano:

We are in receipt of a letter from Mr. William Purvis dated January 30, 1997 regarding a holiday greeting card disseminated by CellPro during the month of December 1996.

By way of background, it is important to point out that the card was not intended to be a promotional piece. We have procedures in place to assure that all promotional materials meet regulatory requirements. Simply put, this card slipped through the cracks. We are taking steps to assure that this type of problem does not occur again.

The company will take the following action to remedy the observations noted in Mr. Purvis's letter.

1. A copy of the letter will be distributed to employees responsible for preparation and distribution of advertising and promotional materials.

2. In the future, we will assure that all materials distributed by the company are properly reviewed and are in accord with the labeling reviewed and approved by the FDA.

We are confident that our present procedures, coupled with the training of our staff, will assure that only appropriate materials meeting all regulatory requirements are distributed by CellPro. If you have any further questions in this regard, please do not hesitate to call me.

Sincerely,

Monica S. Krieger, Ph.D.
Director, Regulatory Affairs

signed copy sent to FDA MSKrieger

FROM: MONICA KRIEGER
TO: EXECUTIVE STAFF, MARKETING, CLINICAL
SUBJECT: FDA LETTER/CORRECTIVE ACTION -FEBRUARY 13, 1997

ATTACHED PLEASE FIND A COPY OF THE LETTER THAT WE SENT TO THE FDA REGARDING OUR CHRISTMAS CARD. PLEASE NOTE THAT WE SHOULD ASSURE THAT ALL MATERIALS THAT MAY BE SENT TO CUSTOMERS (CLINICAL SITES) THAT COULD BE CONSTRUED AS PROMOTIONAL LITERATURE SHOULD BE REVIEWED THROUGH THE PROCESS ESTABLISHED IN THE MARKETING DEPARTMENT. IF YOU HAVE ANY QUESTIONS, PLEASE DON'T HESITATE TO CALL ME.

sent via E-mail
2/13/97

CHAPTER 4
ADVISORY ACTIONS

CONTENTS

SUBCHAPTER
WARNING LETTERS

PURPOSE

The purpose of this chapter is to specify the agency's enforcement procedures governing the use of Warning Letters.

BACKGROUND

Various forms of letters containing warnings of violations have been used throughout the history of FDA. However, such letters were sparingly used until 1967, when District Directors were authorized to issue such correspondence. A proposed regulation was published in 1978 that would have formally defined the agency's procedures and prescribed the use of two forms of Warning Letters (Notice of Adverse Findings Letters and Regulatory Letters).

The proposal was withdrawn in 1980; however, the criteria for such letters were placed in the RPM and used by the agency until May 1991. On May 23, 1991, the agency implemented the single Warning Letter system to replace the two letter warning system. The Warning Letter system placed more authority, responsibility, and flexibility at the district level concerning enforcement strategy decisions than previous procedures.

Warning Letter - A written communication from FDA notifying an individual or firm that the agency considers one or more products, practices, processes, or other activities to be in violation of the Federal FD&C Act, or other acts, and that failure of the responsible party to take appropriate and prompt action to correct and prevent any future repeat of the violation, may result in administrative and/or regulatory enforcement action without further notice.

PROCEDURES

When it is consistent with the public protection responsibilities of the agency and depending on the nature of the violation, it is FDA's practice to afford individuals and firms an opportunity to voluntarily take appropriate and prompt corrective action prior to the initiation of enforcement action. Warning Letters are issued for the purposes of achieving this voluntary compliance and establishing prior notice (see definitions in RPM Chapter 10 and the RPM section on "Prior Notice". The use of the Warning Letter and the prior notice policy are based on the expectation that a majority of individuals and firms will voluntarily comply with the law. The agency position is that Warning Letters should only issue for violations of regulatory significance; i.e., those violations that may actually lead to enforcement

action if not promptly and adequately corrected.

The Warning Letter was developed and initiated to correct violations of the statutes or regulations. Also available to the agency are enforcement strategies which are based on the particular set of circumstances at hand and may include sequential or concurrent FDA enforcement actions such as recall, seizure, injunction, administrative detention, and/or prosecution to achieve correction. Despite the significance of the violations, there are a number of circumstances which may preclude the agency from pursuing any further enforcement action following the issuance of a Warning Letter. For example, the violation may be serious enough to warrant the issuance of a Warning Letter and subsequent seizure; however, if the seizable quantity fails to meet the agency's threshold value, the agency may choose not to pursue a seizure. In this instance, the Warning Letter would appropriately document prior warning if adequate corrections are not made and enforcement action is warranted at a later time.

Responsible officials in positions of authority in regulated firms have a legal duty to implement whatever measures are necessary to ensure that their products, practices, processes, or other activities are in compliance with the law. Under the law such individuals are presumed to be fully aware of their responsibilities. Consequently, responsible individuals should not assume that they will receive a Warning Letter, or other prior notice, before FDA initiates enforcement action.

FDA is under no legal obligation to warn individuals or firms that they or their products are in violation of the law prior to taking enforcement action, except in a few specifically defined areas. When acting under the authority of the Radiation Control for Health and Safety Act (RCHSA), FDA is required by law to provide a written notification to manufacturers when the agency discovers products that fail to comply with a performance standard or that contain a radiation safety defect. Due to the legal requirements of the RCHSA, minor variations on the procedures specified below may occur.

A Warning Letter is informal and advisory. It communicates the agency's position on a matter, but it does not commit FDA to taking enforcement action. For these reasons, the agency does not consider Warning Letters to be final agency action on which FDA can be sued.

There are instances when issuance of a Warning Letter is not appropriate, and, as previously stated, issuance of such a letter is not a prerequisite to taking enforcement action. Examples of situations where the agency will take enforcement action without necessarily issuing a Warning Letter include:

1. The violation reflects a history of repeated or continuous conduct of a similar or substantially similar nature during which time the individual and/or firm have been notified of a similar or substantially similar violation.
2. The violation is intentional or flagrant.
3. The violation presents a reasonable possibility of injury or death.
4. The violations, under Title 18 U.S.C. 1001, are intentional and willful acts that once having occurred, cannot be retracted; also such a felony violation does not require prior notice. Therefore, Title 18 U.S.C. 1001 violations are not suitable for inclusion in Warning Letters.

In certain situations, the agency may also take other actions as an alternative to, or concurrently with, the issuance of a Warning Letter. Additional instructions concerning the issuance of Warning Letters in specific product areas are located in various agency compliance programs and compliance policy guides.

AGENCY POLICY ON THE ISSUANCE OF WARNING LETTERS

Warning Letters should be issued only for violations of "regulatory significance." The threshold for determination of what constitutes "regulatory significance" is that failure to adequately and promptly achieve correction to the Warning Letter may be expected to result in enforcement action. It is recognized that despite the seriousness of the violations there are a number of circumstances which may mitigate against the Agency pursuing further regulatory action following the issuance of a Warning Letter. For example, the violation may be serious enough to warrant the Warning Letter and subsequent seizure. If, however, the seizable quantity fails to meet the Agency's threshold value, the Warning Letter would be appropriate to document prior warning if adequate corrections aren't made and subsequent enforcement action is warranted, i.e., injunction or prosecution.

WARNING LETTERS TO OTHER GOVERNMENT AGENCIES

All government establishments should be held to the same standards as non-governmental establishments. However, although the public health standards are identical, the process utilized to ensure compliance with these standards may vary. The Agency believes that government establishments will achieve and maintain a higher rate of voluntary compliance with FDA regulations compared to non-government establishments. Therefore, the most efficient use of our limited enforcement resources is

Division of Compliance Policy has developed 17 criteria points.

The audit form, see Exhibit 21, can assist in insuring uniformity in the issuance of warning letters. Through use of an audit, strengths and weakness can be addressed and plans for correction implemented.

EXHIBITS

Imports
4-1 Sample Warning Letter (WL) - Violative Shipments
4-2 Sample WL Language (WLL) - Failure to Hold Entry Misrepresentation
Sample WLL - Distribution Prior to Release
Sample WLL - Misrepresentation
Sample WLL - Standard of Identity/Foreign Language

Biologics
4-3 Sample WL - Blood or Plasma
4-4 Sample WLL - Computer Software
Sample WLL - Source Plasma

Drugs
4-5 Sample WL - Misbranded
4-6 Sample WL - Tamper-Resistant Packaging
4-7 Sample WLL - Sterile drugs/CGMP
Sample WLL - DESI Drug/NDAs and ANDAs
Sample WLL - Homeopathic Drugs

Devices
4-8 Sample WL #1 - GMPs and MDR
4-9 Sample WL #2 - GMPs and MDR
4-10 Sample WL #3 - GMPs and MDR
4-11 Sample WL #4 - GMPs and MDR
4-12 Sample WL #5 - GMPs and MDR
4-13 Sample WL #6 - GMPs and MDR
4-14 Sample WL #7 - GMPs and MDR
4-15 Sample WL #8 - GMPs and MDR
4-16 Sample WL #9 - X-Ray Assemblers

Foods
4-17 Sample WLL - Standard of Identity
Sample WLL - Undeclared Additive
Sample WLL - Seafood Misbranding
Sample WLL - Labeling
Sample WLL - Sulfites in Potatoes
Sample WLL - Infant Formula
Sample WLL - Interstate Sanitation
Sample WLL - Insanitary Conditions
Sample WLL - NLEA

Cosmetics
4-18 Sample WLL - Color Additives

Veterinary Medicine
4-19 Sample WL - Medicated Feed Mill
4-20 Sample WLL - GMP Veterinary Drug
Sample WLL - Producer Warning Letter
Sample WLL - Misbranding
Sample WLL - Dealer Warning Letter

Other
4-21 WL Audit Report Form

SUBCHAPTER
UNTITLED LETTERS

AGENCY POLICY ON ISSUANCE

There are some specific circumstances in which the agency has a need to communicate with regulated industry about documented violations that do not meet the threshold of regulatory significance. Therefore, when circumstances warrant the issuance of an untitled letter to a member of an FDA-regulated industry, the letter should be in a format that clearly distinguishes it from a Warning Letter. The essential elements of this untitled letter are:

1. Not titled;
2. May be issued by any appropriate agency compliance official;
3. No statement that FDA will advise other federal agencies of the issuance of the letter so that they may take this information into account when considering the awarding of contracts;
4. No warning statement that failure to take prompt correction may result in enforcement action;
5. No mandated district follow-up;
6. Time frames for correction are not specified; and
7. A written response may be an option, but is not necessary.

The following types of correspondence should be issued as untitled letters and not as warning letters:

1. Letters sent to an entire industry, such as the letter on excessive glazing of seafood. Letters issued to put an entire industry "on notice" should be untitled letters.
2. The district may issue a brief untitled letter with the FDA-483 attached to assure that top management of a firm (i.e. president, CEO, etc.) has a copy of the FDA-483 when the original FDA-483 was not issued to top management during the inspection. Since this correspondence is only a brief transmittal letter it is not considered a warning letter. If

significant deviations are found, a warning letter should be sent and not an untitled letter.

UNTITLED LETTERS ISSUED TO INDUSTRY ON ILLEGAL PROMOTIONAL ACTIVITIES

If a center is willing to support further Agency regulatory action if the violative practice doesn't cease, a warning letter and not an untitled letter should be issued for illegal promotional activities such as the promotion of a device or drug which has not been approved by FDA for commercial distribution and making representations that the device or drug is safe or effective for such purposes. If the center is not prepared to support regulatory action should a firm ignore a letter issued for illegal promotional activities, neither a warning letter nor an untitled letter should be used. An alternate approach would be to alert the district office of the violation and request that they bring the promotional activity to the attention of the firm on the next scheduled visit. This way if the district inspection reveals additional problems, this violation may be included as part of their regulatory action plan, should the firm fail to make appropriate corrections. If the problem is deemed to be more urgent the district could also request a meeting with the firm to discuss the violations.

192199 HFI-3

January 11, 1994

WARNING LETTER
CHI-857-94

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Vernon R. Loucks, Jr.
Chairman and CEO
Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, IL 60015

Dear Mr. Loucks:

An inspection of the corporate headquarters of the Fenwal Division of Baxter Healthcare was conducted on November 2, 1993, by Investigator Nalini Patel. The inspection covered the Baxter Bone Marrow Collection Kit. The Bone Marrow Kit is a medical device as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (Act).

The inspection revealed that the Baxter Bone Marrow Collection Kit is misbranded under Section 502(o) of the Act for failure to submit to FDA a 510(k) Premarket Notification for significant changes made to the design of the device. The size and composition of the filters were changed and a pre-filter was added to the collection container of the kit in May 1993. Under Title 21, Code of Federal Regulations, 807.81(a)(3)(i), a premarket notification submission is required when a change or modification is made to a device that could significantly affect the safety or effectiveness of the device.

This is not intended to be an all inclusive list of violations which may exist at your firm. It is your responsibility as a manufacturer of medical devices to ensure that your operations are in full compliance with all requirements of the Act and regulations promulgated thereunder.

We request that you take prompt action to correct this violation. If such action is not taken, we are prepared to invoke regulatory sanctions provided for by law including seizure and/or injunction. No pending application for premarket approval (PMA) or quality assurance evaluation requests for procurement by government agencies will be approved until adequate corrective actions have been taken with respect to the above violation.

Please advise this office in writing within 15 working days of receipt of this letter as to the specific actions your firm has taken or intends to take to correct this violation. If corrective action cannot be taken within 15 days, state the reason for the delay and time within which the corrections will be completed.

Your reply should be sent to Jerome Bressler, Director, Compliance Branch, 300 S. Riverside Plaza, Suite 550 South, Chicago, Illinois 60606.

Sincerely,

Raymond V. Mlecko
District Director

cc: EF
cc: SJ
cc: HFM-600
cc: HFR-230
cc: HFI-35
cc: HFR-MW150
cc: HFA-224
cc: SDE
cc: CHI-DO R/F (2)

RVM/JB/SDE/dag

CERTIFICATE OF SERVICE

I, Gerard M. O'Rourke, do hereby certify that on June 5, 1997, I caused to be served copies of the foregoing SUPPLEMENTAL DECLARATION OF DR. MONICA S. KRIEGER IN OPPOSITION TO PLAINTIFFS' MOTION FOR PERMANENT INJUNCTION AND IN SUPPORT OF ALTERNATIVE MOTION FOR STAY OF INJUNCTION upon the following counsel of record by the means indicated:

BY HAND:

William Marsden, Esquire
POTTER, ANDERSON & CORROON
Hercules Building
Wilmington, DE 19801

BY FEDERAL EXPRESS:

Steven Lee, Esquire
KENYON & KENYON
One Broadway
New York, NY 10004

Michael Sennett, Esquire
BELL, BOYD & LLOYD
70 West Madison Street
Chicago, IL 60602

Donald R. Ware, Esquire
FOLEY, HOAG & ELIOT
One Post Office Square
Boston, MA 02109

Gerard M. O'Rourke, Esquire
Del. I.D. Number 3265